UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/283,318	03/31/99	SMITH J	

JACK V SMITH
PO BOX 5895
ASHEVILLE NC 28813

HM22/0913

EXAMINER	
FOLEY,S	
ART UNIT	PAPER NUMBER
1648	12

DATE MAILED:
09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/283,318	SMITH, JACK V.	
	Examiner	Art Unit	
	Shanon A. Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,8 and 11-18* is/are pending in the application.

4a) Of the above claim(s) *5 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after an advisory action. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/01 has been entered.

Claims 5, 8, and 11-18 are pending. Claims 5 and 8 are withdrawn from consideration due to the non-election of species I, drawn to a liquid assay in the restriction requirement in paper no. 4.

Double Patenting

Claims 5 and 8 of this application conflict with claims 1 and 2 of Application No. 09/843422. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Objections

Claim 14 is objected to because of the following informalities: "can", in line 1 should be followed by "be". Appropriate correction is required.

Claim 16 is objected to because of the following informalities: "reagents solutions" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite. It cannot be determined if the claim is directed to detecting any HIV antibodies present in a sample or whether the claim is drawn to detecting HIV antibodies to the antibodies in the reagents. The reagent "anti-HIV", line 5, is presumed to be HIV antibodies and "anti-HIV antigen conjugated to microparticles" in lines 3 and 4 is presumed to be HIV antibodies conjugated to microparticles. If the matrix used to quantify HIV antibodies in a sample already has HIV antibodies on it, how will the matrix distinguish between the reagent antibodies and the sample antibodies? Also, the claim states that the reagents added to the matrix "produces a detectable response in the presence or absence of anti-HIV at the assay and control lines". If the reagent HIV antibodies have already produced a line in the assay portion of the matrix, how will one determine whether a sample is positive for HIV antibodies or not? Is the method drawn to detecting sample antibodies to the reagent antibodies? Also, are all of the reagents (buffer, anti-IgG, ect.) successively impregnated onto the matrix in the order listed? This rejection affects all dependent claims 12-14.

Also in claim 11, is the "anti-IgG" in lines 3 and 4, IgG antibody or an antibody to IgG antibody?

Claim 12 is vague and indefinite because it cannot be discerned which "antibody" in the preamble is being referred to from claim 11. Is this group of "antibodies" referring to the antibodies detected from the test sample? Also, the claim recites that the antibody "can be" selected from a particular selection. It is unclear whether or not the antibodies are required to be selected from the ones listed in the claim or not.

Claim 13 states that the anti-HIV antigen "can be" selected from a group. Due to the passive claim language, it is unclear whether or not the anti-HIV antigen is required to be selected from the ones listed in the claim or not.

Claim 14 also is indefinite for reciting passive claim language "can".

Claim 15, step (a) is drawn to "successively" impregnating a carrier matrix with reagent solutions, but does not state what the reagents are or in what order they should be applied.

Claim 16 is drawn to what the reagents are for claim 15, but does not state in which order they should be applied to the matrix in step (a) of claim 15.

Claims 17 and 18 are indefinite for reciting passive claim language "can be" in lines 1 and 5 of claim 17 and line 1 of claim 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman-Kien et al. (5,122,446) and Ishigawa et al. (6,063,564).

Claims 11-14 are drawn to a method for detecting the presence of HIV antibodies in a test sample by impregnating a carrier matrix with a buffer, anti-IgG, anti-HIV, anti-HIV antigen and IgG conjugated to microparticles and determining the quantity of HIV present by comparing control and assay lines. Claims 15-18 are drawn to a method for determining the presence of HIV antibodies in a test sample with a test strip by impregnating the test strip with a buffer, HIV antigen-conjugated beta-galactosidase, and a substrate indicator.

Friedman-Kien et al. teaches a method for detecting the presence of HIV antigens in a test sample by using ELISA, column 4, line 52 to column 5, line 30, and western blot analysis in example 4, columns 13-17. HIV antigens are immobilized on nitrocellulose membrane strips. Dry strips are soaked in Tris buffered saline, and blotting buffer, before samples are added. Biotin conjugated goat anti-human IgG was added to the strips before avidin-horseradish peroxidase was used to detect the presence of color. The sample strips are compared to the controlled strips provided by the manufacturer. Friedman-Kien et al. does not teach anti-HIV, or anti-HIV conjugated to microparticles, or anti-IgG to detect the presence of HIV antibodies in a test sample. However, Ishigawa et al. uses HIV antigen, and anti-HIV, β-gal bound to IgG polystyrene balls, in column 10, lines 38-67 and HIV antigen p17 bound to β-gal in column 14, lines 19-column 15, line 5 to detect HIV antibodies or antigens in a sample, see claims 1-7. One of ordinary skill in the art at the time the invention was made would have motivated to modify the ELISA/western blot method taught by Friedman-Kien et al. by using antigen and/or IgG-conjugated microparticles taught by Ishigawa et al. to increase the surface area between the

analyte of interest and the solid phase coated with the substance combined with an enzyme to accelerate the reaction time. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation in producing the claimed invention because Ishigawa et al. teaches insoluble carrier used to detect analytes is selected from a wide variety of conventional solid phase means such as sticks and ELISAs, see column 4, lines 37 to column 7, line 63. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
September 10, 2001

James C. Housel 9/10/01
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600